

## **REMARKS**

### **A. Claim rejections – 35 U.S.C. §112, second paragraph**

Claims 3 and 8 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action states that the claims are confusing because they recite "collagen mixture," which reads as a mixture of different types of collagen. According to the Office Action, the specification at page 9, line 14 defines the collagen mixture as collagen and appropriate solvent.

Applicant has amended claims 3 and 8 by removing the term "collagen mixture" and specifying that the collagen in claims 1 and 6 may be mixed with an appropriate solvent.

### **B. Claim rejections – 35 U.S.C. §103**

Claims 1, 3, 4, 6, 8, and 9 are rejected under 35 U.S.C. §103 as obvious over US Patent No. 5,292,362 ('362). According to the Office Action, '362 teaches a composition in the form of a liquid or gel comprising collagen and a sugar selected from an oligosaccharide such as fructose or a polysaccharide, wherein the composition is UV irradiated. '362 does not teach the specific sugars recited in claims 1 and 6, but the Office Action states that both '362 and the present application disclose fructose and sucrose to be equivalent to any other sugar. Based on this, the Office Action states that it would have been obvious to provide a composition comprising collagen and sugar, and to select the sugar according to the properties and intended use of the composition.

To the extent that the rejection applies to the amended claims, Applicant respectfully traverses. In order to establish a prima facie case of obviousness, a prior art reference (or combined references) must teach or suggest all the claim limitations. '362 does not teach or suggest the use of gamma irradiation in preparation of a cross-linked collagen composition. As such, the reference does not render the claims obvious.

Claims 1, 3, 4, 6, 8, and 9 are rejected under 35 U.S.C. §103 as obvious over US Patent No. 5,632,773 ('773). According to the Office Action, '773 teaches a composition in the form of a gel comprising collagen and a sugar such as sucrose, wherein the composition is gamma or UV irradiated. '773 does not teach the specific sugars recited in claims 1 and 6, but the Office Action states that the present application discloses fructose and sucrose as equivalent to any of the sugars recited in those claims. Based on this, the Office Action states that it would have been obvious to provide a composition comprising collagen and sugar, and to select the sugar according to the properties and intended use of the composition.

To the extent that the rejection applies to the amended claims, Applicant respectfully traverses. '773 teaches the use of UV or gamma radiation as means for polymerizing a collagen composition. The present invention, however, teaches the use of gamma irradiation in the sterilization of a collagen composition. As such, the amended claims state that gamma irradiation occurs subsequent to UV irradiation as a means of sterilizing the composition. This amendment is supported at page 7, lines 1-2 of the application as filed.

Claims 5 and 7 are rejected under 35 U.S.C. §103 as obvious over '362 or '773, either individually or in view of US Patent No. 5,716,633 ('633). The Office Action states that neither '362 nor '773 teach gamma irradiation subsequent to UV irradiation. However, the Office Action goes on to state that Applicant has not shown superior or unexpected results from the exposure of the composition to gamma radiation subsequent to UV radiation. The Office Action goes on to state that '663 teaches a collagen hydrogel that is exposed to gamma radiation and placed under UV light, and that this teaching provides motivation for performing both gamma and UV irradiation.


To the extent that this rejection applies to the amended claims, Applicant respectfully traverses. As stated above, the present invention teaches the use of gamma radiation subsequent to UV radiation as a means of sterilizing a collagen composition. '362, '773, and '663 all teach UV or gamma radiation as interchangeable means for cross-linking collagen. None of the references contemplate the use of gamma irradiation subsequent to UV irradiation, much less the use of gamma irradiation as a means of sterilizing a cross-linked collagen composition. As such, the references do not render the present invention obvious.

**CONCLUSION**

In view of the foregoing, it is submitted that the present claims are in condition for allowance. Accordingly, Applicant respectfully requests that a Notice of Allowance be issued.

Respectfully submitted,  
Perkins Coie LLP

Date: 1/24/05

  
\_\_\_\_\_  
Patrick D. Morris, Ph.D.  
Registration No. 53,351

**Correspondence Address:**

Customer No. 34055  
Perkins Coie LLP  
P.O.Box 1208  
Seattle, WA 98111-1208  
Telephone: (310) 788-9900  
Facsimile: (310) 788-3399